REVIVAL CLINICAL RESEARCH

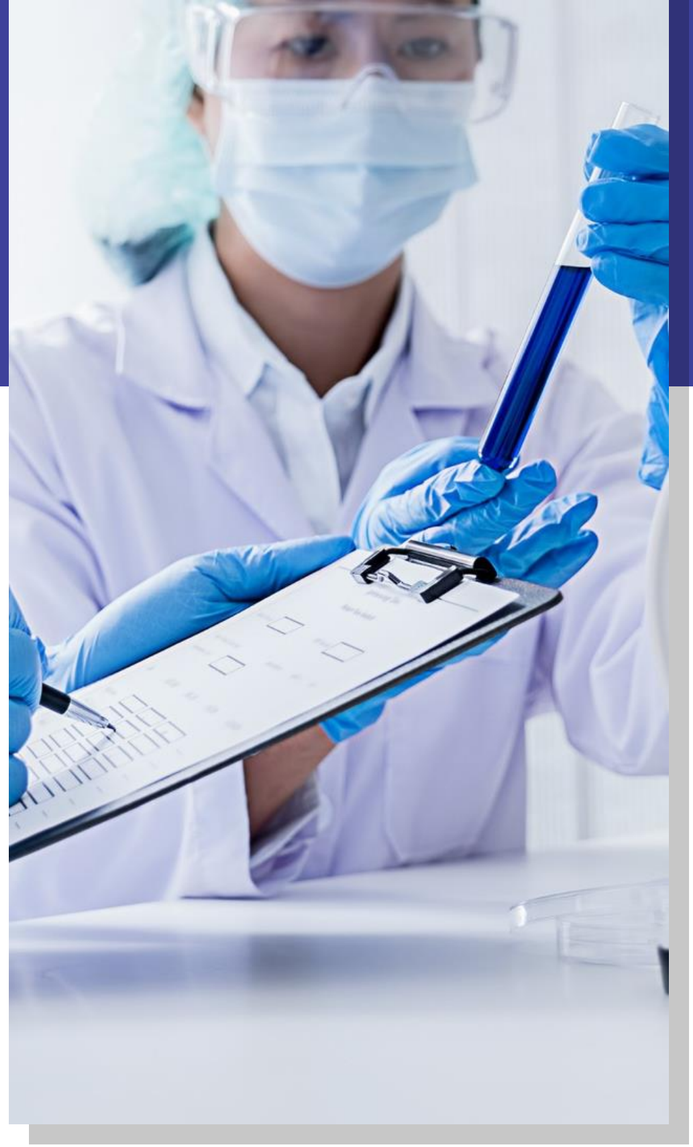
Audience: Doctors

REVIVAL CLINICAL
RESEARCH

How Clinical Trials Work

What is a clinical trial?

Clinical trials answer questions about how well a treatment or therapy works and/or how safe it is by monitoring its effect on people (often through bloodwork and other tests, as well as checking for symptoms and side effects). The people in clinical trials are called clinical trial participants and are volunteers who may be healthy or have a specific illness or condition.



The Four Phases of a Clinical Trial

Each clinical trial phase seeks to answer different questions about the treatment being tested and builds upon research and results. Usually when you join a clinical trial, you'll be in just one phase of the trial, however some clinical trials give the option to participate in more than one phase. Clinical trials are reviewed by regulatory agencies for safety and effectiveness, and by ethical review boards. The sections below provide more information about each phase.

Safety & Dosage

Few weeks - several months

Phase 1 trials study a potential treatment in a small group of participants who are either healthy or have a specific condition. They evaluate the treatment's safety, determine a safe dosage, and identify serious side effects. This is the first time the treatment is tested in people.

20 to 100 participants

Effectiveness & Side Effects

Several months - 2 years

Phase 2 trials expand to a larger group of participants and evaluate the treatment's effectiveness at treating a specific condition and study its side effects, while continuing to monitor for safety. For this reason, only participants with the specific condition may enroll.

several hundred participants

Effectiveness & Adverse Reactions

Usually 1-4 years or longer

Phase 3 trials continue to evaluate a treatment's safety, effectiveness, and side effects by studying it among different populations with the condition and at different dosages. The potential treatment is also compared to existing treatments, or in combination with other treatments to demonstrate whether it offers benefit to the trial participants. Once completed, the treatment may be approved by regulatory agencies.

300 to 3,000 participants

Safety & Effectiveness

Usually 1 or more years

After a treatment has been approved by regulatory agencies, it continues to be monitored for safety, effectiveness, risks, benefits, and optimal use when used by participants in the general public with the condition as part of their everyday life.

several thousand participants

Types of Clinical Trials

Interventional

Researching the use of new treatments

Interventional trials are likely what come to mind when you think about clinical trials. They must be done before treatments can be approved by regulatory agencies and prescribed by doctors. Participants are assigned to a treatment group and receive one or more treatments (such as the study treatment, a placebo, or control). This allows the research team to evaluate and understand the safety and effects of the treatment and answer specific health questions.

Observational

Observing outcomes of existing treatments

In this type of study, the research team observes and collects information from participants about their existing treatment and daily lives. The data may be related to their health, habits, or how the treatment affects their condition over time. In observational trials, participants are not assigned to a treatment group, and instead are already using the treatment as part of their regular medical care. A patient registry is a type of observational trial.

How Can You Help Advance Medicine?

Revival Clinical Research seeks physicians to serve as Principal and Sub Investigators of phase II-IV clinical research trials. We are a multi-specialty clinical research site that will assist in identifying potential trials, submitting budgets and contracts, completing essential documents, institutional review board (IRB) submissions, vendor selection, and staff training.

Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products, and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis, or relieving disease symptoms.

How can you help advance medicine?

Phase II

The drug or treatment is given to a larger group of people to determine its effectiveness and further evaluate its safety.

Phase III

The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information to allow the drug or treatment to be used safely.

Phase IV

Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

What is needed of the physician?

- Perform physical exams and tests according to the study protocol
- Review and sign off on study-related lab results
- Attend in-office/virtual study site initiation meetings, study monitoring visits, and close-out visits. The pharmaceutical company requires about an hour of your time for these periodical visits.
- Provide oversite of all study subjects participating in the trial and study staff facilitating the visits.

Benefits:

- Professional development and recognition
- Role in the evolution of medicine
- Introduce new treatment options to your patients
- Increase patient volume
- Compensation for conducting study visits

Questions or interest, contact

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